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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/886,954	06/21/2001	Maureen J. Charron	96700/667	6743

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EXAMINER	
NICKOL, GARY B	
ART UNIT	**PAPER NUMBER**
1642	

DATE MAILED: 12/30/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/886,954	CHARRON ET AL.	
	Examiner	Art Unit	
	Gary B. Nickol Ph.D.	1642	

-- *The MAILING DATE of this communication appears on the cover sheet with the correspondence address* --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on 17 October 2003.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-20 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-20 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

Request for Continued Examination

Paper No. 12_22_2003

The request filed on 09-30-03 for a Continued Examination (RCE) under 37 CFR 1.114 based on parent Application No. 09/886954 is acceptable and a RCE has been established. An action on the RCE follows.

Claims 1-20 are pending and are currently under consideration.

Priority

A review of the parent application (US Application No. 09/516,493; filed 03-01-2000) did not provide support for the amino acid sequence set forth in SEQ ID NO:1. Hence, the instant application and examination of the claimed methods is based on a priority date of **June 21, 2001**. If applicant disagrees with any rejection set forth in this office action based upon the above priority date, applicant is invited to submit evidence pointing to the serial number, page and line where support can be found establishing an earlier priority date.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 4-10, 11, and 14-20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which

applicant regards as the invention. The recitation of "defect in cell proliferation" (Claims 1 and 11) is indefinite as the specification does not clearly define what is included and excluded as a defect in cell proliferation. The specification teaches (page 6, line 35) that defects in cell proliferation include "without limitation" a number of abnormal cell conditions (e.g. hyperplasia, pre-neoplastic lesions, and neoplasia); however, such examples are *specifically* non-limiting and therefore do not particularly point out and distinctly claim the subject matter. Hence, the metes and bounds of what is considered a "defect in cell proliferation" cannot be determined. This rejection can be obviated by amending Claim 1 and 11 to incorporate the subject matter of Claim 2 and 12.

Claims 1-5, and 11-14 are also rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: a active step for detecting GLUTx expression either by using an antibody that is reactive with GLUTx (Claim 6) or using a nucleic acid probe which hybridizes to nucleic acid encoding GLUTx (Claim 8). This rejection can be obviated by amending Claims 1 and 11 to incorporate the subject matter of Claims 6 and 8.

Claims 1-20 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The written description in this case only sets forth a method for determining whether a

subject has *endometrial* cancer comprising assaying for GLUTx expression. Thus, the written description is not commensurate in scope with the claims drawn to detecting GLUTx expression in a genus of cell proliferation defects including, but not limited to, any and all neoplasms, pre-neoplastic lesions, and or adenocarcinomas.

The specification teaches (page 9, lines 30+) that a "defect in cell proliferation" refers to an abnormality in cell proliferation, including an abnormality in the arrangement, development, morphology, multiplication, number, organization, proliferation, shape, or size of cells. The specification further teaches that examples of defects in cell proliferation include, without limitation, hyperplasia, pre-neoplastic lesions, and neoplasia. The specification further teaches (page 7, line 25) that neoplasia includes "cancer". Hence, the claims are broadly drawn to quantifying GLUTx expression in any all tissues including any and all adenocarcinomas for the purposes of detecting a defect in cell proliferation. However, the written description only reasonably conveys the quantification of GLUTx expression in one particular species of cancer-endometrial adenocarcinomas (page 43, lines 5+). The instant disclosure of GLUTx expression in a single species of endometrial adenocarcinoma fails to adequately describe the scope of the claimed genus (any adenocarcinomas or neoplasm), which encompasses a substantial variety of subgenera (including, but not limited to mammary adenocarcinomas, lymphocytic leukemia, myeloid leukemia, lymphomas, and melanomas..see page 7, line 20 of the disclosure). A description of a genus of cancerous tissues that express differential amounts of GLUTx may be achieved by means of a recitation of a representative number of such tissues that falls within the scope of the genus. However, the instant specification fails to provide a sufficient written description of other members of the genus of neoplastic tissues that express GLUTx. Since the

disclosure fails to describe the common attributes or characteristics that identify members of the genus, and because the genus is highly variant, the disclosure of one specific adenocarcinoma is insufficient to describe the genus. Thus, one of skill in the art would reasonably conclude that the disclosure fails to provide a representative number of species to describe and enable the genus as broadly claimed.

Vas-Cath Inc. v. Mahurkar, 19USPQ2d 1111, clearly states "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention*. The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed.*" (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See *Vas-Cath* at page 1116). As discussed above, the skilled artisan cannot envision the other members of the encompassed genus of adenocarcinomas and neoplasms that express GLUTx, and therefore conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method of isolating it. The compound itself is required. See *Fiers v. Revel*, 25 USPQ2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016.

One cannot describe what one has not conceived. See *Fiddes v. Baird*, 30 USPQ2d 1481 at 1483. In *Fiddes*, claims directed to mammalian FGF's were found to be unpatentable due to lack of written description for that broad class. The specification provided only the bovine sequence.

Therefore, only a method for determining whether a subject has *endometrial* cancer comprising assaying for GLUTx expression, but not the full breadth of the claims, meets the written description provision of 35 U.S.C. §112, first paragraph. Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 U.S.C. §112 is severable from its enablement provision (see page 1115).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-20 are rejected under 35 U.S.C. 102(e) as being anticipated by Baughn *et al.* (US 2003/0171275 A1, December 20, 2000).

Baughn *et al.* teach methods of detecting a defect in cellular proliferation by using agents to assay for an amino acid sequence with 100% sequence identity to SEQ ID NO:1 (see attached sequence comparison) including agents such as antibodies labeled with detectable markers and nucleic acid probes (DNA or RNA) which hybridize to nucleic acid encoding GLUTX (see paragraphs 0246-0251, 0256). Baughn *et al.* further teach diagnostic assays to monitor patients being treated for a defect in cell proliferation with the used of labeled antibodies (para. 0246, 0248) specific for SEQ ID NO:1 or hybridization probes (para. 0255) which encompasses a method for assessing the efficacy of therapy to treat a defect in cell proliferation in a subject who

has undergone or is undergoing treatment for a defect in cell proliferation. Baughn *et al.* teach (page 27, 1st column, line 4) that such defects in cellular proliferation include cerebral neoplasms and prostate cancer wherein the latter encompasses an adenocarcinoma.

The following prior art is provided and made of record (although not relied upon) is considered pertinent to applicant's disclosure:

US Provisionals:

60/172,572 (December 20, 1999)

60/172,000 (December 23, 1999)

60/173,758 (December 30, 1999)

60/176,083 (January 14, 2000)

60/177,332 (January 21, 2000)

60/181,625 (February 10, 2000)

If a copy of a provisional application listed on the bottom portion of the accompanying Notice of References Cited (PTO-892) form is not included with this Office action and the PTO-892 has been annotated to indicate that the copy was not readily available, it is because the copy could not be readily obtained when the Office action was mailed. Should applicant desire a copy of such a provisional application, applicant should promptly request the copy from the Office of Public Records (OPR) in accordance with 37 CFR 1.14(a)(1)(iv), paying the required fee under 37 CFR 1.19(b)(1). If a copy is ordered from OPR, the shortened statutory period for reply to this Office action will not be reset under MPEP § 710.06 unless applicant can demonstrate a substantial delay by the Office in fulfilling the order for the copy of the provisional application. Where the applicant has been notified on the PTO-892 that a copy of the provisional application is not readily available, the provision of MPEP § 707.05(a) that a copy of the cited reference will be automatically furnished without charge will not apply.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gary B. Nickol Ph.D. whose telephone number is 703-305-7143. The examiner can normally be reached on M-F, 8:30-5:00 P.M..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa can be reached on 703-308-3995. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Gary B. Nickol, Ph.D.
Examiner
Art Unit 1642

GBN
December 22, 2003